IN THE CLAIMS:

Please amend the claims as follows:

1. (Currently amended) A clinical research data management system for a plurality of users comprising:

a computer system operable to service user requests and provide users with information responsive to the user requests;~~,~~ and

a database coupled to the computer system, wherein the database is operable to store user data and study data, ~~and~~ wherein the study data includes candidate data, specimen data, event data and at least one dataset, and wherein the dataset is defined using metadata.

2. (Currently amended) The system of claim 1 wherein the ~~database is operable to store~~event data ~~related to~~includes scheduled events, ~~and~~ unscheduled events, or both.

3. (Original) The system of claim 1 wherein the computer system is operable to send and receive electronic messages between at least two users.

4. (Original) The system of claim 3 wherein the computer system is operable to limit communication of electronic messages between users having a specific role in connection with a specific study.

5. (Original) The system of claim 1 wherein the candidate data includes data relating to a plurality of candidates and the specimen data includes data relating to a plurality of specimens wherein the system is operable to associate each specimen with a candidate.

6. (Original) The system of claim 1 wherein the user data includes at least one role associated with each user.

7. (Currently amended) The system of claim 1 wherein the user data includes at least one role associated with each user, wherein the role is selected from the group of data monitor, enroller, data editor, study administrator, ~~and~~ system administrator, and user administrator.

8. (Currently amended) The system of claim 6 wherein the role defines data access rights granted at a dataset definition level, data item definition level, or both.

9. Cancelled.

10. Cancelled.

11. (Currently amended) The system of claim 6 wherein the database is operable to identify at least a portion of the user data as privacy data and wherein the role defines a ~~users ability~~user's capability to view privacy data.

12. (Original) The system of claim 1 wherein the database includes at least one display form associated with the dataset and wherein the display form is defined using metadata.

13. (Original) The system of claim 1 wherein the database includes at least two display forms associated with the dataset and wherein the display forms are defined using metadata.

14. (Original) The system of claim 13 wherein a first display form is formatted to render the dataset on a first display device, and a second display form is formatted to render the dataset on a second display device.

15. (Original) The system of claim 13 wherein a first display form is formatted to render the dataset in a first language, and a second display form is formatted to render the dataset in a second language.

16. (Original) The system of claim 1 wherein the database stores an audit record of data access including information relating to the data accessed, user, date and time.

17. (Original) The system of claim 1 wherein at least a portion of the user data or study data is stored in the database in an encrypted format.

18. (Currently amended) A clinical research data management method for a plurality of users comprising:

defining at least one dataset using metadata; and

storing user data and study data in a database coupled to a computer system, wherein the study data includes candidate data, specimen data, event data and the at least one dataset ~~and wherein the dataset is defined using metadata~~.

19. (Currently amended) The method of claim 18 wherein the ~~database is operable to store~~event data ~~related to~~includes scheduled events, ~~and~~ unscheduled events, or both.

20. (Original) The method of claim 18 wherein the computer system is operable to send and receive electronic messages between at least two users.

21. (Original) The method of claim 20 wherein the computer system is operable to limit communication of electronic messages between users having a specific role in connection with a specific study.

22. (Original) The method of claim 18 wherein the candidate data includes data relating to a plurality of candidates and the specimen data includes data relating to a plurality of specimens wherein the system is operable to associate each specimen with a candidate.

23. (Original) The method of claim 18 wherein the user data includes at least one role associated with each user.

24. (Currently amended) The method of claim 18 wherein the user data includes at least one role associated with each user, wherein the role is selected from the group of data monitor, enroller, data editor, study administrator, ~~and~~ system administrator, and user administrator.

25. (Currently amended) The method of claim 23 wherein the role defines data access rights granted at a dataset definition level, data item definition level, or both.

26. Cancelled.

27. Cancelled.

28. (Currently amended) The method of claim 23 wherein the database is operable to identify at least a portion of the user data as privacy data and wherein the role defines a ~~users ability~~user's capability to view privacy data.

29. (Original) The method of claim 18 wherein the database includes at least one display form associated with the dataset and wherein the display form is defined using metadata.

30. (Original) The method of claim 18 wherein the database includes at least two display forms associated with the dataset and wherein the display forms are defined using metadata.

31. (Original) The method of claim 18 wherein a first display form is formatted to render the dataset on a first display device, and a second display form is formatted to render the dataset on a second display device.

32. (Original) The method of claim 18 wherein a first display form is formatted to render the dataset in a first language, and a second display form is formatted to render the dataset in a second language.

33. (Original) The method of claim 18 wherein the database stores an audit record of data access including information relating to the data accessed, user, date and time.

34. (Currently amended) A clinical research data management system for a plurality of users comprising:

a computer system operable to service user requests and provide users with information responsive to the user requests, and

a database coupled to the computer system, wherein the database is operable to store user data and study data relating to a plurality of studies, wherein study data includes candidate data, specimen data, event data and at least one dataset, wherein user data includes at least one role associated with each user, and wherein the role defines data access rights granted at ~~one of~~ a dataset definition level, ~~and~~ data item definition level, or both.

35. (Currently amended) A clinical research data management system for a plurality of users comprising:

a computer system operable to service user requests and provide users with information responsive to the user requests, and

a database coupled to the computer system, wherein the database is operable to store user data and study data relating to a plurality of studies, wherein study data includes candidate data, specimen data, event data and at least one dataset, wherein user data includes at least one role associated with each user and wherein the computer system is operable to limit communication of electronic messages between ~~user~~ users having a specific role in connection with a specific study.

36. (Currently amended) A clinical research data management system for a plurality of users comprising:

a means for servicing user requests and providing users with information responsive to the user requests, and

a database for storing user data and study data, ~~and~~ wherein the study data includes candidate data, specimen data, event data and at least one dataset, and wherein the dataset is defined using metadata.

37. (Currently amended) A clinical research data management system for administering a plurality of studies, the system having a computer system operable to service user requests and provide users with information responsive to the user requests and a database with a flexible database structure that facilitates the study definition process for a ~~broad range~~variety of studies, the system comprising:

~~(a)~~ presentation creation means operable to provide users with dynamic information,

~~(b)~~ application control and navigation means operable to service user requests,

~~(c)~~ data access means operable to access information that resides in a system database wherein the database is operable to store user data and study data and wherein the study data includes candidate data, specimen data, event data and at least one dataset and wherein the dataset is defined using metadata.

38. (Currently amended) The system of claim 37 further comprising:

~~(d)~~ application and data security means operable to limit users access to information in the system database.

39. (New) A system as in claim 1, wherein the database has tables with fields associated with one or more of dataset definitions, dataset storage, dataset display, data item definitions, capabilities and roles, and events.

40. (New) A method as in claim 18, wherein the database has tables with fields associated with one or more of dataset definitions, dataset storage, dataset display, data item definitions, capabilities and roles, and events.

41. (New) A system as in claim 34, wherein the database has tables with fields associated with one or more of dataset definitions, dataset storage, dataset display, data item definitions, capabilities and roles, and events.

42. (New) A system as in claim 35, wherein the database has tables with fields associated with one or more of dataset definitions, dataset storage, dataset display, data item definitions, capabilities and roles, and events.

43. (New) A system as in claim 36, wherein the database has tables with fields associated with one or more of dataset definitions, dataset storage, dataset display, data item definitions, capabilities and roles, and events.

44. (New) A method as in claim 40, wherein each of the events relates to an occurrence in time of an interaction with a study subject for which the at least one dataset is collected.

45. (New) A method as in claim 40, wherein an event is an initial visit, a surgery, a follow up visit or treatment.

46. (New) A method as in claim 40 further comprising tracking the events, wherein each of the events is either scheduled or unscheduled such that, if scheduled, the events are predefined, wherein each of the events has a status associated therewith for tracking progress.

47. (New) A system for clinical research data management, comprising:
a multi-tiered computer application including:
a client tier having presentation, presentation logic and user interface portions,

a middle tier including application control, business logic and data access portions,

a data tier including a database and database management portion, wherein the database is configured for storing user data and study data, wherein the study data includes candidate data, specimen data, event data and at least one dataset, and wherein the dataset is defined using metadata; and

a channel for communicating data including a data network, wherein the client tier, middle tier and data tire are linked via the channel and enabling access and interaction for clinical research by geographically disparate users.

48. (New) A method in a computerized system for clinical research data management, comprising:

defining roles for a clinical study and assigning respective ones of the roles to users of the system for clinical research data management;

managing role-based authentication and authorization, wherein a role has capabilities commensurate therewith;

defining one or more datasets for the clinical study using metadata;

defining a schedule of events for the clinical study, wherein an event has a status associated therewith;

storing the datasets in a database within the system for clinical research data management, the database being configured for maintaining clinical study data including user information, roles, capabilities, candidate data, specimen data, and event data;

imposing role-based restrictions on user access to the clinical study data and on communications between users;

maintaining the status of events by tracking their occurrence and, thereby, monitoring progress of the clinical study.

49. (New) A method as in claim 48 wherein imposing the restrictions on access includes maintaining an audit trail that records users' access information.

50. (New) A method as in claim 49, wherein the access information includes user's identity, time of access, type of access and level of access.

51. (New) A method as in claim 50, wherein a dataset includes data items, and wherein the level of access is a dataset level, data item level, or both.

52. (New) A method as in claim 48, wherein the roles include data monitor, enroller, data editor, study administrator and system administrator.

53. (New) A method as in claim 48, wherein each capability maps to a functional portion of the system for clinical research data management.

54. (New) A method as in claim 53, wherein the functional portions include one or more of backup database, create study, deploy study, close study, open enrollment, close enrollment, define business rules, enroll subject, disenroll subject, view enrollee, export enrollee list, create profile, disable profile, assign role, disable role, export collaborator list, delete user, approve dataset, ,retract approval, view data, edit dataset, add dataset, suspend edit capabilities, reinstate edit capabilities, export dataset.

55. (New) A method as in claim 48, further comprising deploying for the clinical study one or more functional elements of the system for clinical research data management including login, candidate registration, specimen registration, study administration, data monitoring, data administration, data editing, and communication.